

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 16200.0001P1		Date of mailing (day/month/year) 03 APR 2007 FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US05/31876	International filing date (day/month/year) 06 September 2005 (06.09.2005)	Priority date (day/month/year) 07 September 2004 (07.09.2004)
International Patent Classification (IPC) or both national classification and IPC IPC: A01N 55/02(2006.01) USPC: 514/495		
Applicant PURE BIOSCIENCE		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 19 March 2007 (19.03.2007)	Authorized officer James Henry Alstrum-Acevedo Telephone No. (571) 272-5548
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Form PCT/ISA/237 (cover sheet) (April 2005)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/31876

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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International application No.
PCT/US05/31876

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>9-17, 19-20, 25</u>	YES
	Claims <u>1-8, 18, 21-24, 26-29</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-29</u>	NO
Industrial applicability (IA)	Claims <u>1-29</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1, 18, 24, and 27-29 lack novelty under PCT Article 33(2) as being anticipated by Newman et al. (U.S. Patent No. 6,838,095). Newman teaches antimicrobial silver compositions, comprising (a) water, (b) free silver ions; (c) a complexing agent (title; abstract; col. 1, lines 20-37). Silver ions are well known for their antifungal, antiviral, and antibacterial properties (i.e. antimicrobial). Dibasic citrate is a preferred complexing agent, because citrate is a key constituent of the metabolic system, is aggressively drawn into cells throughout the body, and provides an efficient delivery system for spreading silver through the body before decomplexing takes place and gradual release of free silver ions occurs (col. 4, lines 24-33). Ionic silver has been indicated for the treatment of various diseases and conditions (col. 6, lines 10-33) and is especially suitable for oral irrigation systems for consumer use. Such silver-containing oral irrigation systems may be sprayed as a fine stream of water in the mouth to fight infection and heal gums. Aqueous compositions comprising silver citrate dibasic inherently comprise silver dihydrogen citrate, because citrate dibasic will readily undergo equilibrium reaction in water to form dihydrogen citrate and hydroxide ions.

Claims 1-8, 21-24, and 26-29 lack novelty under PCT Article 33(2) as being anticipated by Arata (US 2004/0044073). Arata discloses electrolytically generated silver citrate acne treating compositions, which include silver dihydrogen citrate, in the form of a cosmetic, lotion, emulsion, gel, or soap (title; abstract; [0023]; [0031]; [0078]; claims 26-37).

Claims 2-17, 19-23, and 25-26 lack an inventive step under PCT Article 33(3) as being obvious over Newman et al. (U.S. Patent No. 6,838,095) in view of Gavin et al. (U.S. Patent No. 7,026,308). The teachings of Newman have been set forth above. Newman lacks the teaching of antimicrobial silver compositions comprising (1) surfactant; (2) ethanol; as well as said compositions in the form of an emulsion. Gavin teaches topical anti-microbial compositions for the treatment of dandruff and infections of the skin and scalp, wherein said compositions comprise a polyvalent metal salt of pyridone and a metal ion source. Suitable sources of metal ions include silver (title, abstract; and col. 4, lines 47-48). Generally, antimicrobial agents are included in anti-dandruff shampoos (col. 2, lines 4-6). A variety of carriers may be used in Gavin's invented compositions, including liquid carriers such as ethanol, glycerine, dimethylformamide (DMF), or dimethylsulfoxide (DMSO) (col. 5, lines 14-32). Gavin's compositions may also be aqueous systems (col. 5, lines 41-42) or in the form of a solid powder (col. 5, lines 51-53). The topical carrier in Gavin's compositions may include a surfactant. Suitable surfactants are disclosed from col. 6, line 6 through col. 10, line 49. Volatile carriers may be used in Gavin's formulations too, such as alcohols, ethers, hydrocarbons, etc. (col. 11, line 28 through col. 12, line 63). Optional ingredients which may be included in Gavin's invented compositions include (1) other anti-microbial actives (col. 13, line 43 through col. 14, line 28); (2) suspending or thickening agents (col. 14, line 29 through col. 16, line 3); (3) organic conditions oils, such as hydrocarbon, polyolefin, and fatty ester oils (col. 33, line 24 through col. 36, line 43); and other additional components such as anti-dandruff agents, pH adjusting agents, preservatives, sunscreens, vitamins, thickeners, viscosity adjusting agents, etc. (col. 37, line 33 through col. 38, line 3).